PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Phase 1/2 Study of the Effect of TOT or Solifenacin After Cesa or Vasa on Urge Urinary Incontinence

Trial Acronym

URGE-II

URL of the trial

[---]*

Brief Summary in Lay Language

Urge urinary incontinence can be a disorder caused by destroyed pelvic structures. We repaired the uteri-sacral ligaments (USL) by cesa or vasa. The study evaluates if solifenacin can lead to continence after surgery or if also the pubo-urethral ligaments (PUL) need to be repaired.

Brief Summary in Scientific Language

It was hypothesized that urge urinary incontinence in women is based on the destruction of the uteri-sacral ligaments (USL)and the pubourethral ligaments (PUL). In a preliminary study (URGE I) we repaired the USL by cesa or vasa. Those patients who are still incontinent after cesa and vasa get the repair of the PUL by means of trans-obturator tapes (TOT). That treatment is compared to conservative medical treatment. Cross over after completion of three months is possible if no continence is achieved.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006365**
- Date of Registration in DRKS: **2014/10/01**
- Date of Registration in Partner Registry or other Primary Registry: **2012/11/28**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01737918 (ClinicalTrials.gov)**
- Sponsor-ID: **URGE-II (Klinikum der Universität Köln)**

Health condition or Problem studied

- Free text: **Surgical Treatment of Urge Incontinence**

Interventions/Observational Groups

- Arm 1: **Procedure: TOT**
- Arm 2: **Drug: solifenacin**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **I-II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- cure of incontinence; time frame: 3 months

Secondary Outcome

- improvement of urge symptoms; time frame: 3 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Abt. Beckenbodenchirurgie der Universitäts-Frauenklinik Köln, Köln**
- **Abt. Beckenbodenchirurgie der Universitäts-Frauenklinik Köln, Köln**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/01/31**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **40 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

- prior vasa or cesa operation as part of the URGE I study

- stress urinary incontinence

- mixed urinary incontinence

Exclusion criteria

- **previous urogynecological surgery**
  - **avulsion of cesa or vasa tape**
  - **pregnancy**
  - **neurologic/psychological reasons for incontinence**
  - **body weight >100kg**
  - **syndrome of dry overactive bladder**

Addresses

■ **Primary Sponsor**

Klinikum der Universität Köln

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Study Supervisor
Wolfram H Jager, PhD

Telephone: **[---]***
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E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Wolfram H Jager, PhD

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E-mail: **wolfram.jaeger at uk-koeln.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

[---]*

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 4
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.